### EXPRESS MAIL MAILING LABEL

No. EL953 994882 US

**PATENT** 

Attorney Docket No.: MEE-005

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**APPLICANTS:** 

Adamis et al.

**SERIAL NO.:** 

09/478,099

**GROUP NO.:** 

1632

FILING DATE:

January 5, 2000

**EXAMINER:** 

Baker, A.

TITLE:

Targeted Transscleral Controlled Release Drug Delivery to the Retina

and Choroid

Commissioner for Patents Washington, D.C. 20231

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

#### REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

|             | (1)         | within three (3) months of the <b>filing date</b> of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the <b>date of entry of the national stage</b> as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the <b>first Office action</b> on the merits, or before the mailing of a <b>first Office action</b> after the filing of a request for continued examination under 37 C.F.R. 1.114; or |
|-------------|-------------|--|
| $\boxtimes$ | (2)         | after the period defined in (1) but before the mailing date of a <b>final action</b> or a <b>notice</b> of allowance under 37 C.F.R. 1.311, and  |
|             |             | the requisite Statement is below, <b>OR</b>  |
|             | $\boxtimes$ | the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or   |

11/22/2002 NMOHAMM1 00000049 09478099

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180.00 GP

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|      | (3)            | after the mailing date of a final action or notice of allowance but before the payment of the issue fee, AND |
|------|----------------|--|
|      |                | the requisite Statement is below, AND  |
|      |                | the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.                      |
|      | It is respectf | fully requested that each of the patents and publications listed on the attached Form                        |
| PTO- | 1449, and of   | ther information contained herein, be made of record in this application.                                    |

#### **STATEMENT**

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page <u>and</u> the Statement is required]:

- Each item of information contained in the Information Disclosure Statement was
  first cited in any communication from a foreign patent office in a counterpart
  foreign application not more than three months prior to the filing of the
  Information Disclosure Statement; or
- 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Date: November 20, 2002

Reg. No.: 38,678

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Respectfully submitted,

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SHEET 1 OF 5

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## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MEE-005

APPLICANTS: Adamis et al.

SERIAL NO.: 09/478,099

FILING DATE: January 5, 2000 GROUP: 1632

### U.S. PATENT DOCUMENTS

| EXAM.<br>INIT. |  |           | NAME      | CLASS                | SUB<br>CLASS | FILING DATE IF<br>APPROPRIATE                |   |  |
|----------------|--|-----------|-----------|----------------------|--------------|--|---|--|
| A1             |  | 3,618,604 | 11/9/71   | Ness et al.          | 128          | 260  |   |  |
| -              | A2   | 3,692,027 | 9/19/72   | Ellinwood, Jr.       | 128          | 260  |   |  |
| A3 A4 A5       |  | 3,961,628 | 6/8/76    | Arnold               | 128          | 260  |   |  |
|                |  | 3,963,025 | 6/15/76   | Whitaker et al.      | 128          | 260  |   |  |
|                |  | 4,003,379 | 1/18/77   | Ellinwood, Jr.       | 128          | 260  |   |  |
|                | A6   | 4,014,335 | 3/29/77   | Arnold               | 128          | 260  |   |  |
|                | A7   | 4,146,029 | 3/27/79   | Ellinwood, Jr.       | 128          | 260  |   |  |
| A8 4,177       |  | 4,177,256 | 12/4/79   | Michaels et al.      | 424          | 22   |   |  |
|                | A9 4,180,073 12/25/79 Michaels A10 4,186,184 1/29/80 Zaffaroni |           | 12/25/79  | Michaels             | 128          | 260  |   |  |
|                |  |           | Zaffaroni | 424                  | 14           |  |   |  |
| ·              | A11  | 4,203,442 | 5/20/80   | Michaels             | 128          | 260  |   |  |
|                | A12  | 4,281,654 | 8/4/81    | Shell et al.         | 128          | 260  |   |  |
|                | A13  | 4,360,019 | 11/23/82  | Portner et al.       | 128          | 213 R  |   |  |
|                | A14  | 4,475,916 | 10/9/84   | Himmelstein          | 604          | 890  |   |  |
|                | A15  | 4,544,371 | 10/1/85   | Dormandy, Jr. et al. | 604          | 891  |   |  |
|                | A16  | 4,734,092 | 3/29/88   | Millerd              | 604          | 67   |   |  |
|                | A17  | 4,957,494 | 9/18/90   | Wong et al.          | 604          | 892.1  |   |  |
|                | A18  | 4,959,217 | 9/25/90   | Sanders et al.       | 424          | 473  |   |  |
|                | A19  | 5,061,242 | 10/29/91  | Sampson              | 604          | 118  |   |  |
|                | A20  | 5,236,689 | 8/17/93   | Wong et al.          | 424          | 473  |   |  |
| -              | A21  | 5,266,332 | 11/30/93  | Dong et al.          | 424          | 473  |   |  |
|                | A22  | 5,300,114 | 4/5/94    | Gwon et al.          | 623          | 4  |   |  |
| EXAMINER       |  |           |           |                      | ONSIDERED    | <u>.                                    </u> | • |  |



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## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MEE-005

APPLICANTS: Adamis et al.

SERIAL NO.: 09/478,099

FILING DATE: January 5, 2000 GROUP: 1632

### U.S. PATENT DOCUMENTS

| EXAM.<br>INIT. |          | DOCUMENT<br>NUMBER     | DATE     | NAME                | CLASS  | SUB<br>CLASS | FILING DATE IF<br>APPROPRIATE |
|----------------|----------|------------------------|----------|---------------------|--------|--------------|-------------------------------|
|                | A23      | 5,348,746              | 9/20/94  | Dong et al.         | 424    |              |                               |
|                | A24      | 5,366,454              | 11/22/94 | Currie et al.       | 604    | 890.1        |                               |
|                | A25      | 5,378,475              | 1/3/95   | Smith et al.        | 424    | 473          |                               |
|                | A26      | 5,391,381              | 2/21/95  | Wong et al.         | 424    | 473          |                               |
|                | A27      | 5,443,508              | 8/22/95  | Giampapa            | 623 11 |              |                               |
|                | A28      | 5,445,616              | 8/29/95  | Kratoska et al.     | 604    | 141          |                               |
|                | A29      | 5,466,233              | 11/14/95 | Weiner et al.       | 604    | 890.1        |                               |
|                | A30      | A30 5,475,096 12/12/95 |          | Gold et al.         | 536    | 23.1         |                               |
|                | A31      | 5,582,981              | 12/10/96 | Toole et al.        | 435    | 6            |                               |
|                | A32      | 5,607,418              | 3/4/97   | Arzbaecher          | 604    | 891.1        |                               |
|                | A33      | 5,660,846              | 8/26/97  | Cheikh              | 424    | 423          |                               |
|                | A34      | 5,725,493              | 3/10/98  | Avery et al.        | 604    | 9            |                               |
| _              | A35      | 5,736,152              | 4/7/98   | Dunn                | 424    | 426          |                               |
|                | A36      | 5,756,291              | 5/26/98  | Griffin et al.      | 435    | 6            |                               |
|                | A37      | 5,773,019              | 6/30/98  | Ashton et al.       | 424    | 423          |                               |
|                | A38      | 5,797,898              | 8/25/98  | Santini, Jr. et al. | 604    | 890.1        |                               |
|                | A39      | 5,830,173              | 11/3/98  | Avery et al.        | 604    | 9            |                               |
|                | A40      | 5,840,867              | 11/24/98 | Toole et al.        | 536    | 23.1         |                               |
|                | A41      | 5,869,078              | 2/9/99   | Baudino             | 424    | 423          |                               |
|                | A42      | 5,888,533              | 3/30/99  | Dunn                | 424    | 423          |                               |
|                | A43      | 5,897,878              | 4/27/99  | Dong et al.         | 424    | 473          |                               |
|                | A44      | 5,902,598              | 5/11/99  | Chen et al.         | 424    | 423          |                               |
|                | A45      | 5,993,414              | 11/30/99 | Haller              | 604    | 93           |                               |
| EXAMIN         | EXAMINER |                        |          |                     | IDERED | 1            | <u> </u>                      |



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## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MEE-005

APPLICANTS: Adamis et al.

SERIAL NO.: 09/478,099

FILING DATE: January 5, 2000 GROUP: 1632

### U.S. PATENT DOCUMENTS

| EXAM.<br>INIT. |     | DOCUMENT<br>NUMBER | DATE     | NAME                | CLASS | SUB<br>CLASS | FILING DATE IF<br>APPROPRIATE |
|----------------|-----|--------------------|----------|---------------------|-------|--------------|-------------------------------|
|                | A46 | 6,001,386          | 12/14/99 | Ashton et al.       | 424   | 423          |                               |
|                | A47 | 6,056,734          | 5/2/00   | Jacobsen et al.     | 604   | 891.1        |                               |
|                | A48 | 6,074,673          | 6/13/00  | Guillen             | 424   | 501          |                               |
|                | A49 | 6,120,789          | 9/19/00  | Dunn                | 424   | 426          |                               |
| ***            | A50 | 6,123,861          | 9/26/00  | Santini, Jr. et al. | 216   | 2            |                               |
|                | A51 | 6,165,155          | 12/26/00 | Jacobsen et al.     | 604   | 156          |                               |
|                | A52 | 6,203,523 B1       | 3/20/01  | Haller et al.       | 604   | 93.01        |                               |
|                | A53 | 6,217,896 B1       | 4/17/01  | Benjamin            | 424   | 427          |                               |
|                | A54 | 6,251,090 B1       | 6/26/01  | Avery et al.        | 604   | 9            |                               |
|                | A55 | 6,277,401 B1       | 8/21/01  | Bello et al.        | 424   | 449          |                               |
|                | A56 | 6,283,949 B1       | 9/4/01   | Roorda              | 604   | 288.02       |                               |
|                | A57 | 6,283,951 B1       | 9/4/01   | Flaherty et al.     | 604   | 529          |                               |
| -              | A58 | 6,306,420 B1       | 10/23/01 | Cheikh              | 424   | 422          |                               |
|                | A59 | 6,312,393 B1       | 11/6/01  | Abreu               | 600   | 558          |                               |
|                | A60 | 6,317,630 B1       | 11/13/01 | Gross et al.        | 604   | 20           |                               |
|                | A61 | 6,319,245 B1       | 11/20/01 | Berrigan            | 604   | 891.1        |                               |
|                | A62 | 6,331,313 B1       | 12/18/01 | Wong et al.         | 424   | 427          |                               |
|                | A63 | 6,364,865 B1       | 4/2/02   | Lavi et al.         | 604   | 411          | · · · · ·                     |
|                | A64 | 6,368,626 B1       | 4/9/02   | Bhatt et al.        | 424   | 473          |                               |
| -              | A65 | 6,368,629 B1       | 4/9/02   | Watanabe et al.     | 424   | 482          |                               |
|                | A66 | 6,375,972 B1       | 4/23/02  | Guo et al.          | 424   | 423          |                               |
|                | A67 | 2002/0026176 A1    | 2/28/02  | Varner et al.       | 604   | 891.1        |                               |
| EXAMINER       |     |                    |          | DATE CON            |       |              |                               |



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# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MEE-005

APPLICANTS: Adamis et al.

| DISCLOSURE STATEMENT |     |   |              |               | APPLICANTS: Adamis et al.                |                        |                |                |                            |                          |  |
|----------------------|-----|---|--------------|---------------|--|------------------------|----------------|----------------|----------------------------|--------------------------|--|
| DISCUSSINE STATEMENT |     |   |              |               |  | SERIAL NO.: 09/478,099 |                |                |                            |                          |  |
|                      |     |   |              |               | FILING DATE: January 5, 2000 GROUP: 1632 |                        |                |                |                            |                          |  |
|                      |     |   | U.           | S. PATENT     | DOCUM                                    | ENTS                   |                |                |                            |                          |  |
| EXAM.<br>INIT.       |     | DOCUMENT<br>NUMBER  | DATE         | NAME          | NAME                                     |                        |                | SUB<br>CLASS   | FILING DATE II APPROPRIATE |                          |  |
|                      | A68 | 6,413,540 B1  | 7/2/02       | Yaacobi       |  |                        | 424            | 427            |                            |                          |  |
|                      | A69 | 6,416,777 B1  | 7/9/02       | Yaacobi       |  |                        | 424            | 428            |                            |                          |  |
|                      |     | <u> </u>  | FORI         | EIGN PATE     | NT DOCU                                  | MENTS                  |                |                | <u> </u>                   |                          |  |
| EXAM.<br>INIT.       |     | DOCUMENT<br>NUMBER  | DATE         | COUNTRY       | CLASS                                    | SUB<br>CLASS           | FILING<br>DATE | ABSTRA<br>ONLY | ACT                        | ENGLISH<br>LANG<br>(Y/N) |  |
|                      | B1  | 86/00519 A  | 1/30/86      | wo            |  |                        |                |                |                            | Y                        |  |
|                      | B2  | 91/16869  | 11/14/91     | wo            |  |                        |                |                |                            | Y                        |  |
|                      | В3  | 93/21874  | 11/11/93     | WO            |  |                        |                |                |                            | Y                        |  |
|                      | B4  | 94/05257  | 3/17/94      | wo            |  |                        |                |                |                            | Y                        |  |
|                      | B5  | 94/13305  | 6/23/94      | wo            |  |                        |                |                |                            | Y                        |  |
|                      | В6  | 94/21314 A  | 9/29/94      | wo            |  |                        |                |                |                            | Y                        |  |
| _                    | B7  | 00/38714  | 7/6/00       | wo            |  |                        |                |                |                            | Y                        |  |
| *                    | B8  | 00/40089 A  | 7/13/00      | wo            |  |                        |                |                |                            | Y                        |  |
|                      | В9  | 01/28472 A1   | 4/26/01      | wo            |  |                        |                |                |                            | Y                        |  |
|                      | B10 | 01/28474 A1   | 4/26/01      | wo            |  |                        |                |                |                            | Y                        |  |
|                      | B11 | 01/30323  | 5/3/01       | wo            |  |                        |                |                |                            | Y                        |  |
|                      | B12 | 01/80825 A  | 11/1/01      | wo            |  |                        |                |                |                            | Y                        |  |
|                      |     |   | OTHER A      | ART, JOUR     | NAL ART                                  | ICLES, I               | ETC.           |                |                            |                          |  |
| EXAM.<br>INIT.       | ОТН | ER DOCUMEN  | TS: (Includi | ng Author, Ti | tle, Date, Re                            | levant Pag             | ges, Place o   | f Publicati    | ion)                       |                          |  |
|                      | C1  | Ambati, J. et al. "Diffusion of High Molecular Weight Compounds Through Sclera" Invest. Ophthalmol. Vis. Sci. (2000) 41: 1181-1185. |              |               |  |                        |                |                |                            |                          |  |
|                      | C2  | Canakis et al. "<br>Molecular Wei   |              |               |  |                        | _              |                | f Diff                     | erent                    |  |
| EXAMIN               | ER  |   | •            |               | DATE CO                                  | ONSIDER                | ED             |                |                            |                          |  |



# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MEE-005

APPLICANTS: Adamis et al.

SERIAL NO.: 09/478,099

**DATE CONSIDERED** 

FILING DATE: January 5, 2000 GROUP: 1632

### OTHER ART, JOURNAL ARTICLES, ETC. EXAM. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) INIT. Carrasquillo et al. "Controlled Delivery of Anti-VEGF Aptamer EYE001 with Poly(lactic-co-glycolic) Acid C3 Microspheres" Poster presentation in 2002. C4 The Eyetech Study Group "Preclinical and Phase 1A Clinical Evaluation of an Anti-VEGF Pegylated Aptamer (EYE001) for the Treatment of Exudative Age-Related Macular Degeneration" J. Retinal Vitreous Diseases (2002) 22: 143-152 C5 Jellinek et al. "Inhibition of Receptor Binding by High-Affinity RNA Ligands to Vascular Endothelial Growth Factor" Biochem. (1994) 33: 10450-10456 C6 Jo, B. et al. "Fabrication of Three-Dimensional Microfluidic Systems by Stacking Molded Polydimethylsiloxane (PDMS) Layers" SPIE (1999) 3877: 222-229. C7 Ruckman et al. "2'-Fluoropyrimidine RNA-based Aptamers to the 165-Amino Acid Form of Vascular Endothelial Growth Factor (VEGF<sub>165</sub>)" J. Biol. Chem. (1998) 273: 20556-20567. C8 Santini, J. Jr. et al. "A Controlled-release Microchip" Nature (1999) 397: 335-338.

**EXAMINER**